IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Brett A. Taylor	Confirmation No.: 9705
Application No.: 10/810,610	Group Art Unit: 3738
Filing Date: March 29, 2004	Examiner: Christopher D. Prone
For: ARTHROPLASTY SPINAL PROSTHESIS AND INSERTION DEVICE	Attorney Docket No.: 190637/US - 485335-2

DECLARATION UNDER 37 C.F.R. § 1.132
OF BRETT A. TAYLOR

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria VA 22313-1450

Sir:

I, Brett A. Taylor, hereby declare as follows:

1. I am a citizen of the United States, residing at 18689 Wildhorse Creek Road, Wildwood, Missouri, United States. I have a Bachelor of Science degree in Biology conferred by Yale University in 1988 and a Medical Doctorate from Harvard University Medical School conferred in 1992. I completed a surgical internship at New England Deaconess Hospital in General Surgery in 1993 and my orthopedic residency in the Harvard combined program in 1997, and was Chief Resident of Massachusetts General Hospital Department of Orthopedics in 1998. I completed a spinal fellowship from the Department of Surgery, Thomas Jefferson University in 1999, and upon completion, served as Chief of Spine Surgery in the Department of Orthopedic Surgery in the United States Air Force, stationed at Wilford Hall Medical Center. I was certified by the American Board of Orthopaedic Surgery in 2001 and am presently licensed in Missouri.

2. Presently, I am a private practice orthopedic spinal surgeon at The Orthopedic Center of St. Louis in Chesterfield, Missouri, and am involved in numerous clinical investigations and act as a coinvestigator in the development of both cervical and lumbar disc

replacements for a number of companies including Medtronic, Sofamor-Danek, DePuy, and Johnson & Johnson. I also serve as a consultant to develop spinal technologies for a number of private entities. I have received numerous clinical grants to investigate spinal conditions in a canine model, Nubian goat models, porcine studies, and investigational cell-based treatments for spinal problems. Previously, from 2002 to 2005, I was an assistant professor of orthopedic spine surgery at Washington University School of Medicine, Department of Orthopedic Surgery. I am published with paper presentations as well as lectureships and course directorships and have served as faculty in numerous spine courses to teach spine surgeons the techniques applicable for spinal surgery for spine conditions. I have approximately ten years of professional experience in the field of spine surgery. I am the inventor of one U.S. Patent and one pending U.S. Patent Application related to spinal prosthesis.

3. I have reviewed and am familiar with the present application, the current Office Action mailed March 17, 2008, the Amendment submitted concurrently herewith, the pending claims, and the references cited in the Office Action, including U.S. Patent Nos. 4,932,975 to Main ("Main"); 5,258,031 to Salib ("Salib"); and 6,296,643 to Hopf ("Hopf") as well as U.S. Patent App. Pub No. 2002/0183761 to Johnson ("Johnson"). I am making the following statements as one of ordinary skill in the art in the field of adult spine surgery.

4. Claim 1 recites an arthroplasty prosthesis, comprising first and second bone contacting members configured for engaging opposing articulated bones, and an articulation member supportively associated with the first and second contacting members. The articulation member allows relative pivotal and translational movement between the first and second contacting members over anterior-posterior and lateral pivotal axes, and anterior-posterior and lateral translational axes. Further, the articulation member is configured to permit the translational movement substantially uncoupled from the pivotal movement.

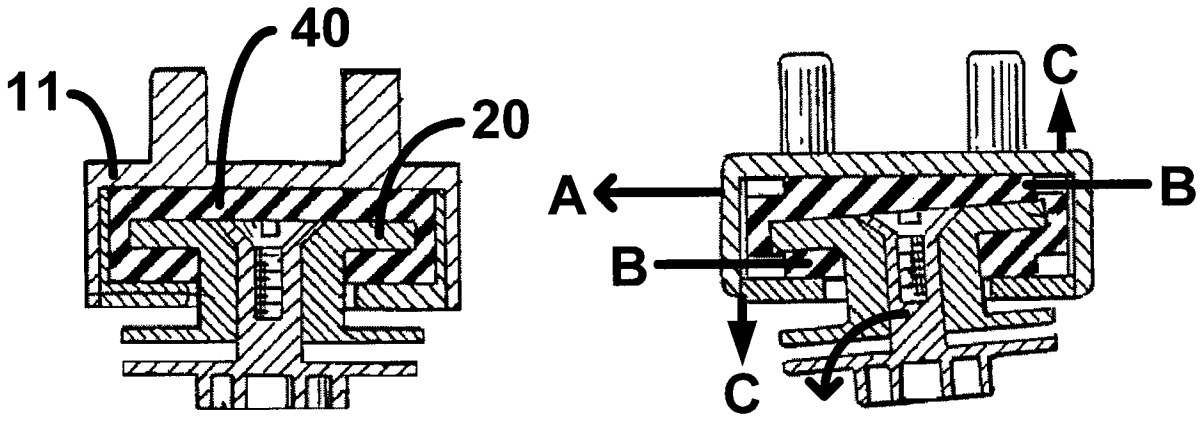
5. The Office Action asserts that Main anticipates claim 1 and discloses an arthroplasty prosthesis comprising a first upper bone contact member 11, second lower bone contact member 11, a central articulation member that allows for pivotal and translational movement of each contact independently comprising a first articulation portion 20 that is in sliding contact with a second articulation portion, and a body prosthetic portion 22.

6. In my opinion, Main does not teach or suggest relative translational movement of bone contacting members. Main states that the two housings 11 are secured against relative movement except to the extent allowed by axial movement, tipping movement, and limited torsional movement of suspension plates 20 in housings 11 (Main, 4:10-15). And none of the axial movement, tipping movement, or torsional movement are similar to the uncoupled translational movement over the anterior-posterior and lateral axes recited in claim 1.

7. Furthermore, it is my opinion that even assuming translational movement of the housings 11 of Main over anterior-posterior and lateral translational axes were possible, such movement would not be uncoupled or substantially uncoupled from pivotal movement, as defined in claim 1. Main teaches a prosthetic vertebral body including a pair of rigid housings, each of which includes a suspension plate 20 surrounded by an elastomeric medium 40. A connecting structure is rigidly attached to the plates 20. The outline of the plates 20 is slightly smaller than the cavity of the housings 11 to allow "a tipping action" as well as torsional movement of the plates 20 in the housings 11 (Main, 3:7-45), and compression and expansion along the spinal axis (Main, 3:45-59). The elastomeric material 40 functions as a suspending medium for the plate 20 within the housing 11 and exerts forces that tend to restrain and cushion relative movement of the plate 20 and housing 11 (Main, 3:51-53).

8. Assuming lateral translational of the housings 11 were possible, any translation of housing 11 would cause plate 20 to rotate and would induce a bias against such rotation, indicating that the two movements are indeed coupled. For example, the figure on the left below shows the vertebral prosthesis of Main in a normal state. As shown in the figure on the right below, as housing 11 is biased for translation in direction A, plate 20 will rotate. The rotation of plate 20 with respect to housing 11 will cause some parts of the elastomeric medium 20 to compress at locations B, as shown below. Because the elastomeric medium 40 functions to restrain relative movement between housing 11 and plate 20, the elastomeric medium will exert torque tending to pivotally bias housing 11 with respect to plate 20 as shown by arrows C and restore the normal relationship between housing 11 and plate 20, as shown in the figure on the right below. As shown in the figures below, any assumed translational motion of housing 11 in the device of Main would indeed be coupled to rotational movement of housing 11 and not

substantially uncoupled from pivotal movement of housing 11, as recited in claim 1. Thus, claim 1 further patentably defines over Main and is allowable.



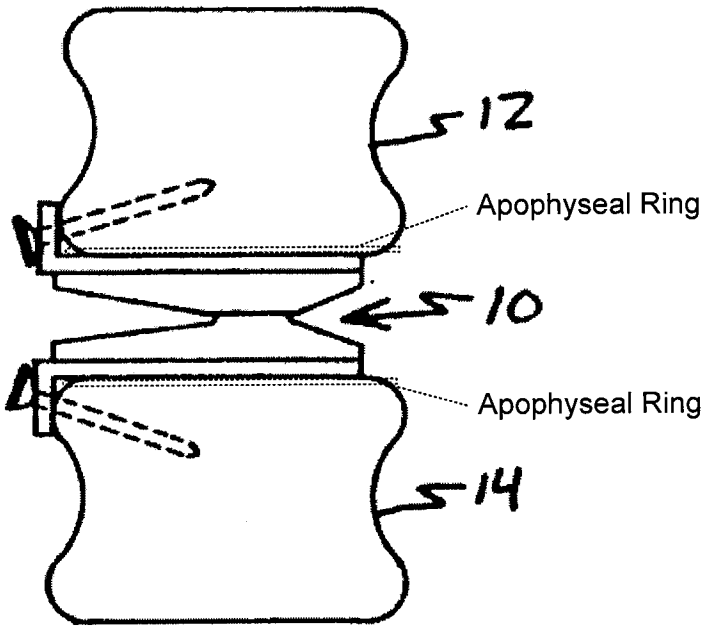
9. Claim 26 recites a spinal prosthesis. The spinal prosthesis comprises first and second bone contacting members configured for engaging opposing first and second bones of the axial skeleton, respectively. The first contacting member comprises a fastener mount portion configured for attaching a bone fastener thereto and vertebral contacting surfaces disposed and oriented for positioning an apophyseal ring of the first bone with respect to the fastener mount portion in an attachment position for attaching the fastener from the fastener mount portion through the apophyseal ring to attach the first contacting member to the first bone.

10. The Office Action asserts that Salib anticipates claim 26 because it discloses an arthroplasty prosthesis comprising a first upper bone contact member 20, second lower bone contact member 22, central articulation members 24 and 44, and diagonally orientated first and second fastener mount holes 40.

11. In my opinion, Main does not teach or suggest vertebral contacting surfaces disposed and oriented for positioning an apophyseal ring of the first bone with respect to the fastener mount portion in an attachment position for attaching the fastener from the fastener mount portion through the apophyseal ring. The apophyseal ring is a narrow mound that substantially encircles the upper and lower surfaces of the vertebrae (Bick, Edgar M. and Copel Joseph W., *The Ring Apophysis of the Human Vertebra*, The Journal of Bone and Joint Surgery,

Vol. 33A, No. 3, July 1951, p. 785; enclosed herewith as Appendix A). The apophyseal ring develops where the fibers of the intervertebral ligaments insert into the ends of the bone (*Anatomy for Surgeons*, 2d Ed., Vol. 3, p. 98; enclosed herewith as Appendix B). The apophyseal ring seldom extends more than a millimeter or two millimeters beyond the longitudinal range of the vertebra itself (Bick, p. 787). As shown below in Fig. 2 of Salib, when the vertebrae are seated against the plates, the screws attach to the vertebral bodies well above the locations of their respective apophyseal rings. Although Salib shows diagonally-oriented first and second fastener mount holes, they are not in a position to allow the fasteners to be attached through the apophyseal ring because the apophyseal ring is located around the bottom edge of the vertebra.

12. As the cited literature indicates, as a person approaches maturity, the apophyseal ring ossifies and finally fuses with the vertebral body such that the apophyseal ring may not be histologically identified. Nevertheless, one of ordinary skill in the art would be able to identify the region of the mature vertebra where the apophyseal ring is located, because apophyseal ring is located at the site at which branching fibers from the long intervertebral ligaments insert into the individual vertebra (Bick, p. 786). The figure below illustrates the region of the vertebra where the apophyseal ring is located.



13. I further declare that all statements made herein of my knowledge are true and all statements made on information and belief are believed to be true; and further that these statements are made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of this application or any patent issuing thereon.

Dated this 17th day of September, 2008.

Declarant: Brett A. Taylor

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